


# Designing the global vaccine supply chain: balancing intellectual property rights with post COVID-19 vaccine equity

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## ABSTRACT

This article aims to propose practical solutions that coordinate the conflicting interests between the global community and the pharmaceutical industry on the intellectual property (IP) waiver for COVID-19 vaccines and facilitate a more equitable vaccine supply chain in the post-COVID-19 world. We critically conducted a narrative literature review to identify procedural and practical issues in the current vaccine supply chain. The search was conducted across various academic disciplines, including biomedical science, life science, law and social science, using resources such as PubMed, Web of Science, Scopus and Westlaw. After screening 731 articles, 55 studies were selected for review. The narrative review revealed several critical barriers that hinder vaccine supply in less-developed countries (LDCs) as follows: (1) WTO Trade-Related Aspects of Intellectual Property Rights (TRIPS) waiver requests may not be granted due to its stringent consensus rule; (2) the current compulsory license system may not work due to the complexity of IP rights covering COVID-19 vaccine technologies; (3) only a few LDCs have domestic companies capable of manufacturing vaccines, and (4) political and economic tensions among countries exacerbate existing barriers to vaccine distribution in LDCs. Based on these findings, we proposed a comprehensive compulsory license system, which combines TRIPS's compulsory license system with the third-party beneficiary mechanism under Common Law. This integrated approach offers a balanced solution that ensures fair compensation for vaccine developers while facilitating broader vaccine access.

## INTRODUCTION

During the COVID-19 pandemic, less-developed countries (LDCs) have experienced more severe COVID-19 cases than developed countries.<sup>1</sup> Most COVID-19 vaccines produced in the USA, the UK and Asia have been provided mainly to developed countries.<sup>2</sup> Intellectual property (IP) monopolies blocked access to COVID-19 vaccines for the LDCs, leading to a shortage of vaccine

## SUMMARY BOX

- ⇒ Less-developed countries (LDCs) face significant challenges in accessing vaccines due to intellectual property monopolies, which have been further complicated by the WTO Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. Furthermore, most LDCs lack the necessary infrastructure, workforce and financial resources to manufacture vaccines domestically.
- ⇒ This study identifies critical barriers in the current vaccine supply chain; it then proposes a practical solution—a comprehensive compulsory license system (CCLS) that combines the TRIPS's compulsory license system with the third-party beneficiary mechanism under Common Law.
- ⇒ Our proposed CCLS offers a balanced approach to ensure fair compensation for vaccine developers while facilitating broader access to vaccines.

supplies for these countries.<sup>3</sup> To address this issue, the WHO initiated the COVID-19 Vaccines Global Access (COVAX) program, a vaccine alliance to secure six billion COVID-19 vaccines for developing countries.<sup>4</sup> However, the COVAX program has been delayed as the production and delivery process of COVID-19 vaccines was slower than expected. Consequently, more than 85 developing countries were expected to wait until those vaccines become fully available, which is expected to be by the end of 2023.<sup>5</sup>

Finally, several developing countries, including India and South Africa, requested a temporary waiver of IP protection on COVID-19 vaccines under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). They called for the right to produce vaccines during the pandemic.<sup>6</sup> More than 100 countries and international organisations supported this proposal, including the vaccine-producing

countries (US, Russia and China), WHO and UNAIDS. However, major vaccine manufacturers such as Pfizer (US)-BioNTech (Germany), Moderna (US), and AstraZeneca-Oxford University (UK) were against such COVID IP Waiver proposal, arguing that the current compulsory licensing system under TRIPS was sufficient. Instead, those major pharmaceutical companies with the UK and the European Union (EU) promised to share more vaccines with low-income and middle-income countries by clarifying and simplifying the existing ways in which governments could implement compulsory licensing.<sup>2</sup>

To break the deadlock, in Rome, G20 leaders declared to support WHO's global vaccination strategy to 'boost the supply of vaccines and essential medical products and inputs in developing countries and remove relevant supply and financing constraints'.<sup>7</sup> Accordingly, WTO's ministerial decision on 17 June 2022 clarified to waive the patent right under Article 28.1 of the TRIPS for the production and supply of COVID-19 vaccines without the consent of the patent holders.<sup>8</sup> However, other than patents, IP rights, including essential know-how for vaccine production, were not waived.<sup>9</sup> This unsatisfactory result was probably due to the difficulties in obtaining the consensus required under the TRIPS for waiving all IP rights at the ministerial conference. Furthermore, the ministerial decision on 17 June 2022 did not include diagnostics and therapeutics essential for helping lower income countries combat the pandemic.<sup>10</sup>

Against this backdrop, this article proposes practical solutions to balance the conflicting interests of the global community and pharmaceutical industry concerning IP waivers and facilitate a more equitable vaccine supply chain.<sup>11-14</sup> To this end, we conducted a comprehensive narrative review to critically identify procedural and practical issues in the current vaccine supply chain. Then, building on these findings, we propose a *comprehensive compulsory license system* (CCLS), complementing the current TRIPS framework with a third-party beneficiary mechanism under Common Law.

Our analysis underscores the urgent need to redesign the global vaccine supply chain, which has predominantly operated to favour a selected group of pharmaceutical companies and developed countries through IP ownership. The proposed CCLS signifies a visionary approach, leveraging legal contracts as a driver to encourage collaborative agreements between aligned governments and pharmaceutical companies, thereby facilitating the construction of 'Regional Vaccine Hubs'. This strategy promises to be a milestone in achieving vaccine equity, bridging gaps and fostering global alliances in the united effort to counter the pandemic.

## REVIEW OF CRITICAL BARRIERS TO VACCINE SUPPLY IN LDCS

A comprehensive narrative literature review was conducted using databases in various academic disciplines, including biomedical science, life science, law

and social science, with resources such as PubMed, Web of Science, Scopus and Westlaw. This approach allowed for a thorough examination of relevant literature for our review.

We developed our search strategy using specific keywords and terms based on expert knowledge in the field. Our search focused on three main categories of keywords: COVID-19, TRIPS and Compulsory License System, with related study keywords and terms searched accordingly:

1. COVID-19: "severe acute respiratory syndrome coronavirus" OR "coronavirus" OR "SARS-CoV-2" OR "Coronavirus Disease" OR "COVID 2019"
2. TRIPS: "Trade-Related Aspects of Intellectual Property Rights" OR "TRIPS Agreement" OR "TRIPS"
3. Compulsory License System: "compulsory licensing" OR "compulsory license" OR "compulsory patent licensing."

We then combined these categories using *Boolean operators* to create the following search strings:

4. (1) AND (2), (1) AND (3), (2) AND (3)

This search strategy enabled us to identify and retrieve relevant literature for our review.

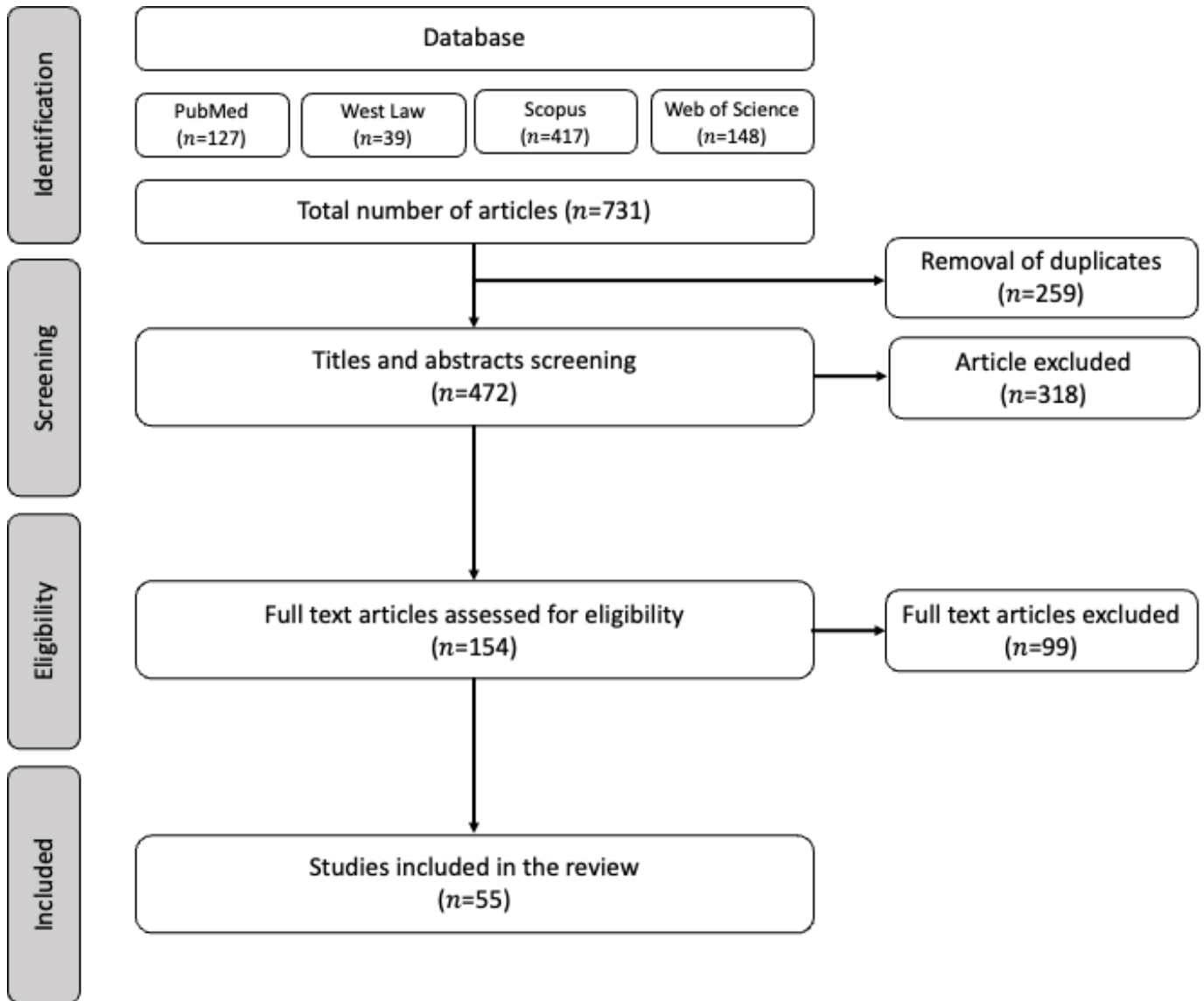
In the search process, we applied specific inclusion and exclusion criteria. The following criteria were used to select articles for the review: (1) language: only articles written in English were considered; (2) publication date: articles published within a defined time range (from 1 May 2020 to 15 April 2023) were included in the review process; (3) peer-reviewed journal: articles were required to be published in peer-reviewed journals that followed established peer review practice.

The initial search produced 731 articles based on our search strategy, and 259 duplicate articles were subsequently excluded. After excluding duplicates, we screened the titles and abstracts of the 472 remaining articles, excluding 318. The final step involved a full-text assessment of 154 articles, 55 articles among which were ultimately included in this review study following the eligibility criteria. [Figure 1](#) shows the study selection process.

A narrative review has identified the following significant hindrances to the vaccine supply for the LDCs.

First, the current TRIPS waiver requests may not be granted in the Ministerial Conference due to the stringent consensus rule. According to Article IX of the Agreement Establishing the WTO,<sup>15</sup> major decisions require consensus among all members, which has never been abandoned in favour of a majority vote.<sup>16</sup> The waiver request, which has garnered support from over 100 countries and various organisations, still faces strong opposition from developed countries, particularly the EU members.<sup>17</sup> The combination of the consensus rule and the inherent complexity of the waiver request will likely hinder its formal adoption.<sup>18</sup>

Second, the current compulsory license system may not work due to the complexity of the IP rights covering the COVID-19 vaccine technologies. Multiple patents and IP



**Figure 1** Flow chart for the selection for inclusion in this review.

rights protect various aspects of these vaccines, such as their production processes, components and technologies.<sup>19–22</sup> This complexity makes it difficult for governments and manufacturers to navigate the licensing process, ultimately slowing the vaccine supply to LDCs.<sup>23</sup>

Third, few LDCs have domestic companies capable of manufacturing vaccines by applying technologies licensed from or waived by pharmaceutical companies. Most LDCs lack basic scientific and technological infrastructure, including research and production facilities, skilled workforces, and financial resources to develop and produce vaccines.<sup>24–26</sup> Technologically, vaccine production requires not only patents, but undisclosed know-how and specific manufacturing technologies that may take months or years to transfer and implement properly.<sup>27</sup> Vaccine development will become dangerous or even impossible without such know-how and confidential information.<sup>28</sup>

Lastly, the deep-seated systemic issues in the global political economy further exacerbate the maldistribution of vaccines to the LDCs. Initially, the IP systems were established to promote innovation.<sup>29</sup> Currently, however, the IP system unfortunately has evolved to protect the interests of vaccine developers, thereby ignoring the urgent need for widespread and equitable distribution.<sup>30–32</sup> This existing framework fosters inequality and stagnation, which overshadow the pressing demands of global public health.

Furthermore, the geopolitical landscape, clouded by ‘vaccine nationalism’, has pushed countries into competition with each other instead of fostering international cooperation.<sup>33</sup> If racing to secure vaccines as national assets rather than global public goods, an equitable global vaccine supply chain will not be obtained. This failure to create a unified front against the pandemic illustrates a complex network of political economy challenges deeply rooted in ‘intellectual monopoly capitalism’, posing

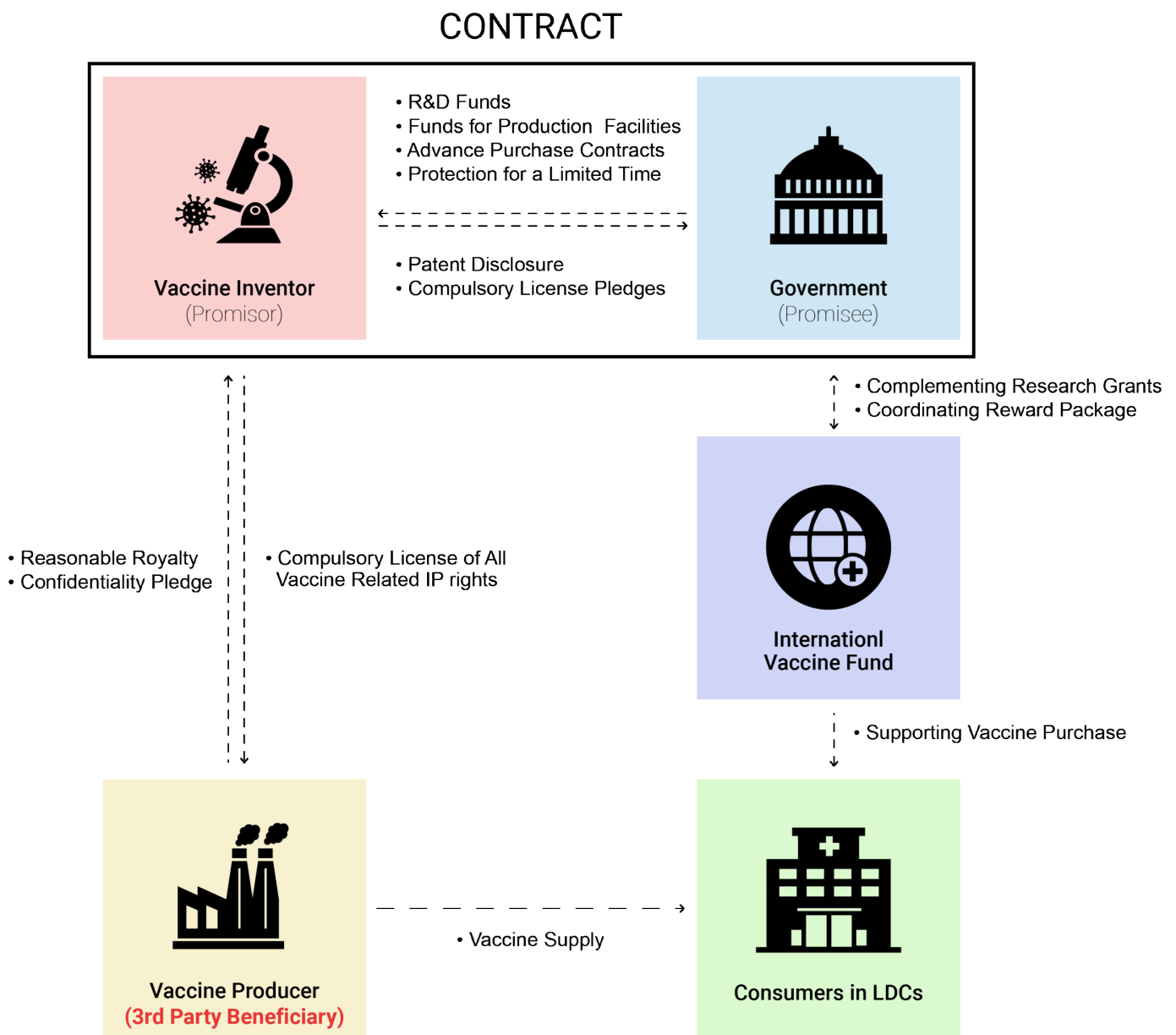
significant hurdles to achieving vaccine equity on a global scale.<sup>34</sup>

In addition, initiatives like COVAX, initially seen as a beacon of hope, have been unable to bridge the gap in vaccine disparities. This is due to a mixture of political issues such as national security and commercial interests, coupled with a lack of transparency and accountability.<sup>35</sup> The effort to build an equitable vaccine supply chain through global initiatives is constantly undermined by a political economy that promotes division and inequality.<sup>36</sup> Moving forward, it is imperative to rethink and redesign the global vaccine supply chain to encourage a cooperative, transparent and equitable system that goes beyond national boundaries and self-serving interests.

### REDESIGNING THE GLOBAL VACCINE SUPPLY CHAIN WITH CCLS

In light of the ongoing challenges of LDCs in accessing COVID-19 vaccines, it is urgently needed to re-evaluate the global vaccine supply chain and devise more efficient and equitable solutions. Therefore, we propose a CCLS that combines the current compulsory license system under TRIPS with an innovative approach to bargaining between governments and vaccine producers. The structure of CCLS is depicted in figure 2.

This system involves five key players: government (promisee), vaccine inventor (promisor), another vaccine producer (third party beneficiary), International Vaccine Fund, and a consumer in the LDCs. Figure 2 shows the flow of relationships between the players.



**Figure 2** Global vaccine supply chain with Comprehensive Compulsory License System. LDCs, less -developed countries.

## GOVERNMENT (PROMISEE) AND VACCINE INVENTOR (PROMISOR)

CCLS is based on the current compulsory license system under the TRIPS and the contract scheme between a government and a vaccine inventor.<sup>37</sup> The government provides funding for research and development (R&D), production facilities and advanced purchase contracts to the vaccine inventor.<sup>38–41</sup> These investments are made to accelerate vaccine development and address concerns related to vaccine equity. In response to this support, the vaccine inventor will pledge a compulsory license of all necessary IP rights for vaccine production and disclose all relevant patents for a limited time. The inventor's pledge to grant licenses to all types of IPs is to be understood as an exceptional extension of the current compulsory license system for patents. Therefore, the additional IPs to be licensed are limited to those necessary to produce the specific vaccines.

## VACCINE INVENTOR (PROMISOR) AND VACCINE PRODUCER (THIRD PARTY BENEFICIARY)

Our proposed structure is inspired by the 'third-party beneficiary mechanism' developed by Common Law.<sup>42</sup> In this mechanism, a contract can be designed to benefit a third party who is not directly involved in the agreement between the promisor and the promisee. It allows the third-party beneficiary to enforce the contract and receive the benefits conferred by the agreement. For example, the relationship between the vaccine inventor and another producer involves licensing and royalty arrangements. The vaccine inventor grants the vaccine producer access to all vaccine-related IP rights through the compulsory license. In return, the other vaccine producer pays a reasonable royalty to the vaccine inventor and pledges confidentiality regarding the IP. This relationship enables the other vaccine producers to manufacture and supply vaccines, contributing to the broader availability of vaccines and promoting vaccine equity.

## INTERNATIONAL VACCINE FUND

It is critical to secure complementary sources of finance, such as the Health Impact Fund (HIF) proposed by Pogge and Hollis.<sup>43</sup> This global agency could facilitate CCLS by complementing research grants from the government to a vaccine inventor; coordinating the reward package for the vaccine inventor based on its evaluation criteria through collaboration with the government; and supporting LDCs without resources for vaccine purchase. Governments need to coordinate and prenegotiate the terms and conditions of their contractual relationship with the vaccine fund to respond to the pandemic without delay.

The proposed vaccine supply chain involves a coordinated effort among governments, an international vaccine fund, vaccine inventors and third-party beneficiaries to enhance vaccine accessibility in the LDCs. A crucial element in initiating this system is the equitable

intentions and leadership of a government, coupled with the financial support from an international vaccine fund. In addition, the coordination and prenegotiation of the terms and conditions of the contract are critical to its success.

The government's proactive involvement will be a cornerstone of making the CCLS a feasible and concrete reality. The establishment of legislative precedents, such as the Bayh-Dole Act in the US, shows the potential to leverage governmental influence to facilitate greater public health benefits.<sup>44</sup> This federal law led non-profit organisations such as universities and small businesses to patent inventions supported by federal funding. However, the Bayh-Dole Act also stipulated that a federal agency can assert the government to control the rights over subject inventions from the patent holder and license them to third parties (35 USC §203—'march-in rights'). This Act already carved a pathway for government control over patent rights, particularly in circumstances that call for substantial health or safety needs.<sup>31</sup>

In addition, the feasibility and viability of the CCLS are significantly bolstered by financial assistance facilitated through an International Vaccine Fund. A notable example is the HIF introduced by Pogge and Hollis.<sup>43</sup> The HIF is a global agency that will reward pharmaceutical innovators based on the global health impact of their products. This novel approach could help to address the growing global health inequity by incentivising the development of new medicines more affordable and accessible to people in developing countries.<sup>45</sup> Its key feature regarding IP policy is an optional registration system that requires innovators to offer their products at the lowest possible production and distribution costs and to provide zero-cost licenses at the end of the reward period.

The CCLS aligns well with the recent suggestions to remodel the pandemic countermeasures ecosystem.<sup>46</sup> As highlighted by Torreale *et al*, it is imperative to eliminate the barriers posed by the current political economy to achieve a balanced global vaccine supply chain.<sup>46</sup> Considering the stakeholders collaborating for epidemic control, including public, private, academic and civic groups and international organisations, Torreale *et al* proposed to develop a sustainable end-to-end ecosystem facilitated by the flexibilities of the IP system for international trade and supported by well-coordinated financing system for networked regional R&D and manufacturing.<sup>46</sup>

What makes the CCLS particularly unique? First, CCLS is free from chronic hurdles and delays in WTO's legislation process because the third party beneficiary is a private, contract-based legal device. So, governments endowed with ample resources and equitable intent could implement the system without delay. A government can coordinate and prenegotiate CCLS terms and conditions to prepare for a pandemic. However, such arrangements will not be cumbersome compared with the international community's efforts to enact and implement rules for the benefit of the LDCs under the TRIPS. Second, CCLS can be used complementarily with an international vaccine

fund, for example, the HIF. Organising and implementing such an international-scale public–private partnership is a huge challenge and adventure. In the meantime, CCLS can fill the gap for more equitable global vaccine distribution. When an international vaccine fund fully functions, it can work complementarily with the government, with more resources and options for the stakeholders of the global vaccine supply chain.

## CONCLUSIONS

In conclusion, our research underscores the urgent need to address the disparities in vaccine access between developed and LDCs during the COVID-19 pandemic. In addition, we have identified significant challenges in the current vaccine supply chain, including the potential difficulty of obtaining the TRIPS waiver due to the stringent consensus rule, the complexities of the IP rights related to COVID-19 vaccine technologies, and the limited capacity of LDCs to manufacture vaccines using licensed or waived technologies from pharmaceutical companies.

To overcome these obstacles and achieve practical solutions that prioritise vaccine equity without undermining IP rights in the post pandemic era, we have proposed the CCLS. The new system integrates the existing compulsory license system under TRIPS with the third-party beneficiary mechanism under Common Law, offering a balanced approach to ensure fair compensation for vaccine developers while facilitating broader access to vaccines.

Even in the post-COVID-19 world, the global community will still struggle to agree on vaccine equity in multilateral trade negotiations. COVID-19 has exposed the constraint of the WHO, and intensified calls to overcome ‘Vaccine Nationalism’. If another pandemic strikes the international community, governments may thus have to include these new compulsory licensing obligations to support vaccine equity in their vaccine development contracts concluded with pharmaceutical companies. Unless the vaccine developers are deprived of their reasonable compensation for inventions, this new compulsory licensing scheme will not deviate from the economic theory of IP rights. There remains room for a bargain between inventors and the governments, that is, licensing all IP rights for vaccine production in return for the massive funding for vaccine research and advance purchase promise from the government and reasonable compensation plus essential pledges of confidentiality from a vaccine producer. A new initiative to create an international vaccine fund to facilitate the CCLS will also play a pivotal role.

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